## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventors:

David J. Ecker, et al.

Serial No.:

Not yet assigned

Group Art Unit: 1637

Filed:

Concurrently herewith

Examiner: Suryaprabha Chunduru

Title:

METHODS FOR RAPID DETECTION AND IDENTIFICATION OF

**BACTERIAL BIOAGENTS** 

EXPRESS MAIL INFORMATION EXPRESS MAIL LABEL NO: EL963417472

DATE OF DEPOSIT: March 25, 2004

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## **INFORMATION DISCLOSURE STATEMENT**

## SIR:

Pursuant to 37 C.F.R. §§ 1.97 and 1.98 and to the duty of disclosure set forth in 37 C.F.R. § 1.56, the Examiner in charge of the above-identified application is requested to consider and make of record the references listed on the attached PTO-1449 forms submitted herewith.

Although the information submitted herewith may be "material" to the Examiner's consideration of the subject application, this submission is not intended to constitute an admission that such information is "prior art" as to the claimed invention.

Copies of the references cited on the attached PTO/SB/08A and PTO-892 forms can be found in the parent case, U.S. Serial No. 10/326,642, filed December 18, 2002.

In accordance with 37 C.F.R. § 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.

No first Official Action has yet been received and it is presumed that none has yet been mailed. No fee or certification is required. 37 C.F.R. § 1.97(b).

Respectfully submitted,

Paul K. Legaard Regis. No. 38,534

Enclosures:

PTO/SB/08A – 8 Sheets PTO-892 (1 Sheet)

Dated: March 25, 2004

Cozen O'Connor 1900 Market Street Philadelphia, PA 19103

Tel: 215.665.6904 Fax: 215.665.2013

Approve: be through 10/31/2002. OMB 0651-0031

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Substitut	e for form 1449A/PT	0		Complete if Known				
				Application Number	10/326,642			
INFO	RMATION	DIS	CLOSURE	Filing Date	December 18, 2002			
STATEMENT BY APPLICANT				First Named Inventor	David J. Ecker			
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	(use as many sh	eets es	necessary)	Examiner Name	Not Yet Assigned			
Sheet	1	of	3	Attorney Docket Number	IBIS0001-106			

			U.S. PATENT	OCUMENTS	
Examiner tritials *	Cite No.	Document Number  Number - Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant
			044404000	5	Figures Appear
	AA	US-5,484,908	01/16/1996	Froehler et al	
	AB	US- 5,502,177	03/26/1996	Matteucci et al	
	AC	US- 5,547,835	08/20/1996	Koster	
	AD	US- 5,605,798	02/25/1997	Koster	
	AE	US- 5,622,824	04/22/1997	Koster	
	AF	US- 5,645,985	07/08/1997	Froehler et al	
	AG	US- 5,691,141	11/25/1997	Koster	
	AH	US- 5,763,588	07/09/1998	Matteucci et al	
	AJ	US- 5,830,653	11/03/1998	Froehler et al	
	AJ	US- 5,849,492	12/15/1998	Rogan	
	AK	US- 5,872,003	02/16/1999	Koster	
	AL	US- 5,965,363	10/12/1999	Monforte et al	<u> </u>
	AM	US- 6,005,096	12/21/1999	Matteucci et al	
	AN	US- 6.007,992	12/28/1991	Lin et al	
	AO	US- 6,028,183	02/22/2000	Lin et al	
		US-			

		Foreign Patent Document		Name of Patentee or	Pages, Columns, Lines, Where Relevant	
Examiner Initials*	Cite No. <sup>1</sup>	Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (# known)	Publication Date MM-DD-YYYY	Applicant of Cited Document	Passages or Relevant Figures Appear	T⁰
	BA	WO97/33000	09/12/97			
	BB	WO97/37041	10/09/97			
	BC	WO98/12355	03/26/98			
	BD	WO98/54751	12/03/98			
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	BF	WO99/31278	06/24/99			
	BG	WO98/20166	05/14/98		·	

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<sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>6</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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Substitute t	for form 1449A/	PTO		Complete if Known			
INFORMATION DISCLOSURE				Application Number	10/326,642		
				Filing Date	December 18, 2002		
STATEMENT BY APPLICANT		First Named Inventor	David J. Ecker				
				Group Art Unit	Not Yet Assigned		
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Sheet	2	of	3	Attorney Docket Number	IBIS0001-106		

		OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS	
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Т2
	CA	Aaserud, D.J., et al., "Accurate base composition of double-strand DNA by mass spectrometry," J. Am. Soc. Mass Spec., 1996, 7, 1266-1269	
	СВ	Bowen, J.E., et al., "The native virulence plasmid combination affects the segregational stability of a theta- replicating shuttle vector in bacillus anthracis var, New Hampshire," J. Appl. Microbiol., 1999, 87, 270-278	
	СС	Hurst, G.B., et al., "Detection of bacterial DNA polymerase chain reaction products by matrix-assisted laser desorption/ionization mass spectrometry," Rapid Commun. Mass Spec., 1996, 10, 377-382	
	CD	Loakes, D., et al., "Nitroindoles as universal bases," Nucleosides and Nucleotides, 1995, 14(3-5), 1001-1003	
	CE	Muddiman, D.C., et al., "Precise mass measurement of a double-stranded 500 base-pair (309 kDa) polymerase chain reaction product by negative ion electrospray ionization fourier transform ion cyclotron resonance mass spectrometry," Rapid Commun. Mass Spec., 1999, 13, 1201-1204	
	CF	Muddiman, D.C., et al., "Length and base composition of PCR-amplified nucleic acids using mass measurements from electrospray ionization mass spectrometry," Anal. Chem., 1997, 69, 1543-1549	
	CG	Sala, M., et al., "Ambiguous base pairing of the purine analogue 1-(2-deoxy-8-D -ribofuranosyt)-imidazole-4-carboxamide during PCR," Nucl. Acids Res., 1996, 24(17), 3302-3306	
,	СН	Van Aerschot, A., et al., "In search of acyclic analogues as universal nucleosides in degenerate probes," Nucleosides and Nucleotides, 1995, 14(3-5), 1053-1056	
	CI	Wunschel, D.S., et al., "Heterogeneity in bacillus cereus PCR products detected by ESI-FTICR mass spectrometry," Anal. Chem., 1998, 70, 1203-1207	
	င္ပ	Mushegian, A.R., et al., "A minimal gene set for cellular life derived by comparison of complete bacterial genomes," Proc. Natl. Acad. Sci. USA, 1996, 93, 10268-10273	
	СК	Wetham, et al., Rapid Communications in Mass Spectroscopy (1988) 12:176-180	

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PTO/SB/08B(10-01)

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Substitu	NFORMATION DISCLOSURE TATEMENT BY APPLICANT  (use as many sheets as necessary)	Complete if Known			
	INFORMATION DISCLOSURE	01 001155	Application Number	10/326,642	
		_		Filing Date	December 18, 2002
STA		PPLICANT	First Named Inventor	David J. Ecker	
				Group Art Unit	Not Yet Assigned
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Sheet	3	of	3	Attorney Docket Number	IBIS0001-106

	,	OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS	<del></del>
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
	a	Cho et al., "Application of the ribonuclease P (RNaseP) RNA gene sequence for phylogenetic analysis of the genus Saccharomonospora," Int'l. J. Systematic Biol. (1998) 48:1223-1230	
	СМ	Matray, et al., "Synthesis and properties of RNA analogs - oligoribonucleotide N3'->P5' phosphoramidates," Nucleic Acids Res. (1999) 3976-3985	
	CN	Li, et al., "Single nucleotide polymorphism determination using primer extension and time of flight mass spectrometry," Electrophoresis (1999) 20:1258-1265	
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Examiner	Date	
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	Substitute	for form 144	8A/PTO					Complete If Known
				Application Number	10/326,642			
	INFORMATION DISCLOSURE STATEMENT BY APPLICANT	ſ	Filing Date	December 18, 2002				
	STAT	<b>TEMEN</b>	T BY	' Al	PPLICANT		First Named Inventor	David J. Ecker
					•		Group Art Unit	1637
		(use as ma	any shee	ts as	necessary)	•	Examiner Name	S. Chunduru
$\overline{}$	Sheet	1		of	5	$\neg$	Attorney Docket Number	IBIS0001-106 (TIGR0005US)

		OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS	
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Τ²
	S1	BAKER, et al., "Review and re-analysis of domain-specific 16S primers," J. Microbiol. Methods (2003) 55:541-555.	
	S2	BENSON, et al., "Advantages of Thermococcus kodakaraenis (KOD) DNA polymerase for PCR-mass spectrometry based analyses," J. Am. Soc. Mass Spectrom. (2003) 14:601-604.	
	S3	BLACK. et al., "Detection of trace levels of tricothecene mycotoxins in human urineby gas chromatography-mass spectrometry," J. Chromatog. (1986) 367:103-115.	
	<b>S4</b>	CAMPBELL and HUANG, "Detection of California serogroup Bunyavirus in tissue culture and mosquito pools by PCR," J. Virol. Methods (1996) 57:175-179.	
	<b>S</b> 5	CHEN, et al., "A universal PCR primer to detect members of the Potyviridae and its use to examine the taxonomic status of several members of the family," Arch. Virol. (2001) 146:757-766.	
١,	\$6	CONRADS, et al., "16S-23S rDNA internal transcribed spacer sequences for analysis of the phylogenetic relationships among species of the genus Fusobacterium," Intl. J. System. Evol. Micrbiol. (2002) 52:493-499.	
	<b>S</b> 7	DASEN, et al., "Classification and identification of Propioibacteria based on ribosomal RNA genes and PCR," System. Appl. Microbiol. (1998) 21:251-259.	
¥	S8	DEFORCE, et al., "Characterization of DNA oligonucleotides by coupling of capillary zone electrophoresis to electrospray ionization Q-TOF mass spectrometry," Anal. Chem. (1998) 70:3060-3068.	
	S9	DEMESURE, et al., "A set of universal primers for amplification of polymorphic non-coding regions of mitochondrial and chloroplast DNA in plants," Mol. Ecol. (1995) 4:129-131.	
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Examiner	Date		•
Signature	Considered		

<sup>\*</sup>EXAMINER: Initial If reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance

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Attorney Docket Number

Complete if Known Substitute for form 1449A/PTO **Application Number** 10/326,642 INFORMATION DISCLOSURE December 18, 2002 Filing Date STATEMENT BY APPLICANT David J. Ecker First Named Inventor **Group Art Unit** 1637 (use as many sheets as necessary) **Examiner Name** S. Chunduru

of 5

Sheet

		OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS	
Examiner	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	S12	FOX et al., "Report of the "Bioterrorism Workshop", J. Microbol. Methods (2002) 51:247-254.	
	S13	GRIFFEY and GREIG, "Detection of base pair mismatches in duplex DNA and RNA oligonucleotides using electrospray mass spectrometry," SPIE (1997) 2985:82-86.	
	S14	GRIFFIN, et al., "Direct genetic analysis by matrix-assisted laseer desorption/ionization mass spectrometry," proc. Natl. Acad. Sci. USA (1999) 96:6301-6306.	
	S15	HANNIS and MUDDIMAN, "Accurate characterization fo the tyrosine hydroxylase forensic allele 9.3 through development of electrospray ionization Fourier transform ion cyclotron resonance mass spectrometry," Rapid. Comm. Mass Spectrom. (1999) 13:954-962.	
	S16	HANNIS and MUDDIMAN, "Genotyping short tandem repeats using flow injection and electrospray ionization Fourier transform ion cyclotron resonance mass spectrometry," Rapid. Comm. Mass Spectrom. (2001) 15:348-350.	
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	S18	HAYASHI, et al., "Phylogenetic analysis of the human gut microbiota using 16S rDNA clone libraries and strictly anaerobic culture based methods," Microbiol. Immunol. (2002) 46:535-548.	
	S19	HOFFMANN, et al., "Universal primer set for the full-length amplification of all influenza A viruses," Arch. Virol. (2001) 148:2275-2289.	
	\$20	ISOLA, et al., "MALDI-TOF mass spectrometric method for detection of hybridized DNA oligomers," Anal. Chem. (2001) 73:2126-2131.	
	S21	JANKOWSKI and SOLER, "Mass spectrometry of DNA: Part 2" Quantitative estimation of base composition," Eur. J. Mass Spectrom. Biochem. Med. Environ. Res. (1980) 1:45-52.	
	S22	KAGEYAMA and BENNO, "Rapid detection f human focal Eubacterium species and related genera by tested PCR method," Microbiol, Immunol. (2001) 45:315-318.	

Examiner	Date	
Signature	Considered	

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		OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS	
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	S23	LITTLE, et al., "Rapid sequencling of oligonucleotides by high-resolution mass spectrometry," J. Am. Chem. Soc. (1994) 116:4893-4897.	
	S24	LIU, et al., "Improving the microdialysis procedure for electrospray ionization mass spectrometry of biological samples," J. Mass Spectrom. (1997) 32:425-431.	
	\$25	MANGRUM, et al., "Solution composition and thermal denaturation for the production of single-stranded PCR amplicons: piperidine-induced destabilization of the DNA duplex," J. Am. Soc. Mass Spectrom. (2002) 13:232-240.	
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	S27	MEIYU, et al., "Detection of flaviviruses by reverse transcriptase-polymerase chain reaction with the universal primer set," Microbiol. Immunol. (1997) 41:209-213.	
	S28	MORICCA, et al., "Detection of Fusarium oxysporum f.sp. vasinfectum in cotton tissue by polymerase chain reaction," Plant Pathol. (1998) 47:486-494.	
	\$29	MUDDIMAN, et al., "Characterization of PCR products from Bacilli using electrospray ionization FTICR mass spectrometry," Anal Chem. (1996) 68:3705-3712.	
	S30	MUDDIMAN, et al., "Length and base composition of PCR-amplified nucleic acids using mass measurements from electrospray ionization mass spectrometry," Anal. Chem. (1997) 69:1543-1549.	
	S31	NAGPAL, et al., "Utility of 16S-23S rRNA spacer region methodology: how similar are interspace regions within a genome and between strains for closely related organisms?," J. Microbiol. Methods (1998) 33:211-219.	
	532	NULL, et al., "Preparation of single-stranded PCR products for electrospray ionization mass spectrometry using the DNA repair enzyme tambda exonuclease," Analyst (2000) 125:619-826.	
	833	NULL, et al., "Evaluation of sample preparation techniques for mass measurements of PCR products using ESI-FT-ICR mass spectrometry," Am Soc. Mass Spectrom. (2002) 13:338-344.	

Examiner Date Signature Considered		
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		OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS	
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	S34	NULL and MUDDIMAN, "Determination of a correction to improve mass measurement accuracy of isotopically unresolved polymerase chain reaction amplicons by electrospray ionization Fourier transform ion cyclotron resonance mass spectrometry," Rapid Comm. Mass Spectrom. (2003) 17:1714-1722.	
	S35	NULL and MUDDIMAN, "Perspectives on the use of electrospray ionization Fourier transform ion cyclotron resonance mass spectrometry for short tandem repeat genotyping in the post genome era," J. Mass Spectrom. (2001) 36:589-606.	
	S36	NULL, et al., "Genotyping of simple and compound short tandem repeat loci using electrospray ionization Fourier transform ion cyclotron resonance mass spectrometry," Anal. Chem. (2001) 73:4514-4521.	
	S37	NULL, et al., "Implications of hydrophobicity and free energy of solvation for characterization of nucleic acids by electrospray ionization mass spectrometry," Anal. Chem. (2003) 75:1331-1339.	
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	S39	POMERANTZ, et al., "Determination of oligonucleotide composition from mass spectrometrically measured molecular weight," J. Am. Soc. Mass Spectrom. (1993) 4:204-209.	
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ST	STATEMENT BY APPLICANT		First Named Inventor	David J. Ecker	
			Group Art Unit	1637	
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## Application/Control No. Applicant(s)/Patent Under Reexamination 10/326,642 ECKER ET AL. Notice of References Cited Art Unit Examiner Page 1 of 1 1637 Suryaprabha Chunduru **U.S. PATENT DOCUMENTS** Date **Document Number** Name Classification Country Code-Number-Kind Code MM-YYYY 514/394 Α US-5 - 200i В US-3-2000 С US-- 2CC D US-Ε US-US-F US-G USн US-US-J US-Κ L US-US-М FOREIGN PATENT DOCUMENTS Date **Document Number** Classification Name Country Country Code-Number-Kind Code MM-YYYY Ν 0 Р Q R S T **NON-PATENT DOCUMENTS** Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages) W

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